REMARKS

35 U.S.C. § 102

Reconsideration and withdrawal of the rejections of record is respectfully requested in view of the remarks contained herein.

Claims 1-7, 9-17, 19-28, 30-38, 38-40, 40-49, 51-59 and 61-65 remain pending in this application.

Item 4A. The Examiner states that "[c]laims 1-4, 9-16, 24, 30-37, 45, 51-58 are rejected under 35 U.S.C. § 102(b) as being anticipated by Henco et al. (U.S. Patent No. 5,057,426) (October 15, 1991).

The Examiner is once again respectfully pointed to the claims of the instant invention. Independent claim 1 as amended is as follows:

> Claim 1. A method for isolating DNA from a biological sample comprising the following ***sequential*** steps:
>
> (a) separating ***the biological material comprising DNA*** from the remainder of the biological sample;
>
> (b) contacting ***the separated biological material comprising DNA*** of step (a) with a hypertonic, high salt reagent so as to form a suspension of ***said biological material containing DNA***;
>
> (c) contacting the suspension of step (b) with a lysis reagent ***so as to lyse the biological material containing DNA*** to form a lysate comprising DNA and non-DNA biological components released from the ***biological material***; and
>
> (d) separating the DNA from the non-DNA biological components in the lysate of step (c) to yield isolated DNA.

(emphasis added)

As indicated, the instant invention teaches a sequential process in which the biological material comprising DNA is separated from the remainder of the biological sample. A plain language reading of this element of the claim indicates that all the biological material containing DNA is separated from the biological material not containing DNA. Thus, the end

products of this first element (or step) of the claim are as follows: biological material containing DNA, and biological material not containing DNA. The following two sequential steps involve first treating the biological material containing DNA with a hypertonic, high salt reagent, followed by lysing this biological material containing DNA. The claim, as supported by the specification indicates that it is only the biological material containing the DNA that is first treated with the hypertonic, high salt reagent, followed by the lysis of this biological material containing the DNA. The novelty of the invention is that this biological material containing DNA is exposed to a lysis reagent only after being treated with a hypertonic, high salt reagent, not before. Thus, in effect, the biological material containing the DNA has never been lysed before step (c) of the claim.

In contrast, contrary to the assertions of the Examiner, Henco does not teach the above elements. Contrary to the assertions of the Examiner, Col. 10, lines 30-40 teaches a different invention from what is taught by the instant invention. Henco in this cite, teaches that DNA- already lysed – will attach to solid matrices at different salt strengths depending on strandedness of the DNA. The aforementioned citation from Henco does not teach any of the elements of the instant invention. Moreover, the teachings of Example 1 of Henco (Col. 11, lines 60-68), do not teach the elements of the instant invention. In example 1, the biological material containing DNA is first placed in a low salt, hypotonic solution over ice (not a hypertonic, high salt reagent), lysed, and then exposed to a hypertonic high salt reagent (see Example 1, Col. 12, lines 5-6). This is contrary to the teachings of the instant invention.

In example 2 of Henco as collectively cited by the Examiner (See Col. 12, lines 20-25), the biological material containing the DNA is already pre-lysed, in that the starting material is a grown and lysed λ-phage/E. Coli culture in which the E.Coli is pre-lysed. When this biological material containing DNA (the supernatant containing both the phage and the DNA from the lysed E.Coli) is exposed to the solution of 0.3 to 0.7 M NaCl, it has already been exposed to a lysis reagent. It is respectfully pointed out to the Examiner that the biological material is not merely the phage; it is both the phage and the pre-lysed E.coli containing DNA. A similar operation conducted as per the teachings and claims of the

instant invention would have involved exposure of the λ-phage/E. Coli culture to the hypertonic, high salt reagent at first, followed by successive lysis steps – a lysis step in which the E. Coli would be selectively lysed, followed by the lysis of the phage using a stronger lysis reagent. In contrast, Henco teaches lysis prior to the treatment with the hypertonic reagent. Thus, Henco et al. does not meet the limitations of the instant claims.

Item 4B. The Examiner states that "[c]laims 1-3, 6-7, 9-10, 13-16, 19-21, 23-25, 27-28, 30-31, 34-37, 40-42, 44-46, 48-49, 51-52, 55-58, 61-63, 65 are rejected under 35 U.S.C. § 102(b) as being anticipated by Miller et al. (Nucleic Acids Res., vol. 16, No. 3, 1988).

It is respectfully pointed out to the Examiner that Miller teaches a process in which the biological material is first lysed in the presence of lysis buffer and SDS, followed by the addition of a high salt, hypertonic reagent (6 M sodium chloride). Miller states that "[b]uffy coats of nucleated cells obtained from anticoagulated blood (ACD or EDTA) were resuspended . . . with ***3 ml of nuclei lysis buffer . . .*** " (emphasis added). Miller goes on to state that "[a]***fter digestion was complete, 1 ml of saturated NaCl was added . . .*** " (emphasis added). Thus, Miller teaches the treatment of the biological material with a lysis reagent first, followed by a hypertonic, high salt reagent. This is contrary to the teachings of the instant invention which teaches a process in which the aforementioned steps are reversed and performed sequentially.

Item 4C. The Examiner states that "[c]laims 1-3, 5-6, 13-17, 25-27, 34-38, 40-42, 44-46, 48-49, 51-52, 55-58, 61-63, 65 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tomita et al.

It is respectfully pointed out to the Examiner that Tomita teaches a process in which the biological material comprising red blood cells and white blood cells is exposed to a hypotonic solution as stated in the specification in Tomita (" . . . erythrocytes were burst in the whole blood under low osmotic pressure," See page 8, paragraph [0073].) The molarity of this 0.5% NaCl w/v solution is less than 0.1 M, allowing the unnucleated red blood cells to burst, as the osmotic pressure is lower in the solution than it is in the red blood cells. This is not a hypertonic solution, in which the osmotic pressure outside the cells is higher than that

inside the cells. The Examiner is respectfully pointed out to the definitions of such reagents in the specification of the instant invention (see page 10 of the specification of the instant invention) that clearly differentiate hypertonic from hypotonic reagents. Thus, Tomita teaches a different invention than what is claimed in the instant invention , and does not teach all the elements of the claims of the instant invention.

35 U.S.C. § 103

Item 9. The Examiner states that "[c]laims 22, 43, and 64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller et al in view of Gray et al.

It is again respectfully pointed out to the Examiner that Miller teaches a process in which the biological material is first lysed, followed by the addition of a high salt, hypertonic reagent (6 M sodium chloride). In contrast, the instant invention teaches a process in which the aforementioned steps are reversed and performed sequentially. As pointed out in the office action dated January 15, 2004, Gray also teaches the isolation of the biological material by lysis prior to the addition of a high salt reagent. Thus, the combined references of Miller and Gray do not recite the teachings of the instant invention.

Based on the remarks above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,

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Date

Sanjay Sitlani
Registration No: 48,489
Attorney for Applicants
Customer No. 26633

Heller Ehrman LLP
1717 Rhode Island Avenue, NW
Washington, D.C. 20036
(202) 912-2000 (phone)
(202) 912-2020 (fax)